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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,572	04/04/2005	Emi Sumida	3190-073	1410

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KILYK & BOWERSOX, P.L.L.C.
400 HOLIDAY COURT
SUITE 102
WARRENTON, VA 20186

EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
08/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,572	SUMIDA ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *12-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/28/05* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/25/05,5/23/05,3/9/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21 are pending. Claims 1-11 are considered on the merits. Claims 12-21 are withdrawn from consideration as being drawn to a non-elected invention. The elected species is "polyamino acid".

Election/Restriction

Claims 12-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Election was made without traverse in Paper No. 7/24/07.

Applicants correctly note that the examiner failed to include claim 18 in any group. Claim 18 should have been designated as its own group, Group V. The examiner regrets this oversight; in the interest of compact prosecution, the restriction has not be reissued and Group I, drawn to a process of making PRP has been examined as follows.

Specification

The disclosure is objected to because of the following informalities: Table 1 and Table 2 appear to be missing data. Please cancel or explain the material. Please note that no new matter may be added to the specification after filing. Appropriate correction is required.

Drawings

The Figures 5, 6, 7, 8-1, 8-29-1, 9-2, 10-1, 10-211-1, 11-2, 12-1, 12-2 are objected to under 37 CFR 1.83(a) because they fail to show details as described in the specification. The figures are of such poor quality as to defy interpretation. Each sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble requires the preparation of PRP, but no production of PRP is seen in the body of the claim. The step of separating the PRP and the sedimented red cells should be included. A suggestion follows below.

A method for preparing platelet-rich plasma from blood comprising:
adding a water soluble polymer to the blood thereby sedimenting the red blood cells in the blood,
separating the sedimented red blood cells and the platelet-rich plasma.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kummer *et al.* [IDS].

The claims are directed to a method of producing a platelet rich plasma from blood comprising:
adding a water soluble polymer to the blood thereby sedimenting the red blood cells in the blood,
separating the sedimented red blood cells and the platelet-rich plasma.

The references are relied upon as explained below.

Kumar *et al.* disclose the addition of modified gelatin (Physiogel M) to blood, sedimenting the red cells, separating the red cells and the PRP (abstract).

It is believed that Physiogel M is a succinylated gelatin product. Evidence to the contrary will be carefully considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,397,479 [IDS] in combination with Maeda *et al.* [U] or US 6,673,629 [A] or Danon [V].

The claims are directed to a method of producing a platelet rich plasma from blood comprising:
adding a water soluble polymer to the blood thereby sedimenting the red blood cells in the blood,
separating the sedimented red blood cells and the platelet-rich plasma.

The references are relied upon as explained below.

US 5,397,479 disclose a method of separating red cells from blood comprising adding aggregators of red cells such as polysaccharides or proteins to the blood (col. 1, l. 60). Specifically disclosed protein aggregators are fibrinogen, gamma globulin (col. 2, l. 29). Also disclosed is the criticality of the concentration of the aggregator used in the sedimentation method (col. 3, ls. 1-19).

Maeda *et al.*, disclose that polyglutamic acid is an aggregator of red cells (abstract). Also disclosed is the criticality of the molecular weight of the polyglutamic acid used in the method in that a polyglutamic acid with a mw of 8000 inhibited aggregation, while a mw of 20,000 accelerated the rate of sedimentation.

US 6,673,629 discloses that polycationic compounds, in particular polyhistidine are aggregators of red blood cells (col. 6, l. 66).

Danon disclose that pLys is an agglutinator of red cells. Also disclosed is the criticality of the molecular weight of pLys and the criticality of the interrelationship of the chemical nature of the polybase and the molecular weight of the polybase (page 289).

The substitution of poly glutamic acid or poly histidine or poly lysine or any polycationic peptide for the aggregator in the method of US 5,397,479 would have been obvious because Maeda *et al.* or Danon or US 6,673,629 disclose that these compounds are aggregators of red cells. This is considered to be the substitution of equivalents known in the art for the same purpose, that is, red cell agglutination/aggregation.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting

claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651
August 20, 2007